June 29, 2018

BY HAND AND ECF

The Honorable Raymond J. Dearie
United States District Court for the Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: ***McGrath v. Bayer HealthCare Pharmaceuticals Inc. et al.*, No. 18-cv-02134**
Request for Pre-Motion Conference

Dear Judge Dearie:

Pursuant to Part III.A of Your Honor's Individual Motion Practices, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer HealthCare LLC (collectively "Bayer") respectfully request a pre-motion conference on Bayer's proposed Rule 12 motions to dismiss all claims for lack of personal jurisdiction and failure to state a claim as described below.

Plaintiff Fails to Allege Contacts between Bayer and New York to Confer Jurisdiction

"[T]o survive a motion to dismiss for lack of personal jurisdiction, the plaintiff[] must . . . . include an averment of facts that, if credited by the ultimate trier of fact, would suffice to establish jurisdiction over the defendant." *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 673 F.3d 50, 59 (2d Cir. 2012) (brackets and internal citations omitted). Doing so requires both satisfying New York's long-arm statute and showing "the exercise of personal jurisdiction [] comport[s] with constitutional due process." *Id.* at 60. The Complaint establishes neither one.

To the contrary, the Complaint's ***only mention*** of New York is that Plaintiff "is a resident of Brooklyn, New York," Compl. p.1 ¶ 1, and the defendants are not. *Id.* p.9 ¶ 38. However, "[i]t is well-settled that residence or domicile of the injured party within New York is not a sufficient predicate for jurisdiction under" New York's long-arm statute. *Troma Entm't, Inc. v. Centennial Pictures Inc.*, 729 F.3d 215, 218 (2d Cir. 2013). Similarly, under the federal Constitution, "mere injury to a forum resident is not a sufficient connection" to confer jurisdiction. *Walden v. Fiore*, 134 S. Ct. 1115, 1125 (2014). These allegations fail to state the required "facts that, if credited by the ultimate trier of fact, would suffice to establish jurisdiction."[1] *Licci*, 673 F.3d at 59.

Even if the Complaint alleged—as it does not—that Plaintiff used Bayer's product in New York, personal jurisdiction would still be lacking. As pled, Bayer did nothing more than develop a

[1] In stipulating to transfer the case here, Bayer "expressly reserve[d] all objections and defenses to the Complaint, including challenges to the Court's personal jurisdiction . . . and all other defenses contained in Fed. R. Civ. P. 12(b)[.]" Order at p.2, N.D. Cal. Doc. 31 (Mar. 22, 2018).

product to be sold in the "nationwide" "stream of commerce." Compl. ¶¶ 16, 84. Such a "stream of commerce" theory cannot support personal jurisdiction under New York's long-arm statute. *See* N.Y. C.P.L.R. § 302(a)(3) (not listing such a theory as permitting suit). And courts across the country have rejected the "stream of commerce" theory as inconsistent with due process. *See, e.g., J. McIntyre Machinery, Ltd. v. Nicastro*, 564 U.S. 873, 878, 880-81 (2011) (plur. opn. of Kennedy, J.). The Supreme Court has instead emphasized that specific personal jurisdiction exists only where the "***defendant*** . . . ***create[s]*** contacts with the forum State." *Walden*, 134 S. Ct. at 1126 (emphasis added). It is not enough that a defendant's "conduct affected plaintiffs with connections to the forum State," *id.* at 1126—which is exactly the situation when defendants manufacture a product for national distribution and New Yorkers happen to use it.

Though Bayer principally seeks dismissal, Bayer alternatively proposes transfer to the District of Delaware, where general jurisdiction exists for many defendants, to cure jurisdictional defects.

Plaintiff Fails to State a Claim for Negligence or Strict Liability

Complete dismissal is further warranted because Plaintiff fails to state a claim for negligence or strict liability. She proclaims with no pled facts that Bayer's FDA-approved imaging contrast agent Magnevist, which is used to help diagnose serious diseases such as cancer and strokes, caused her "Gadolinium Deposition Disease," or "GDD" for short, which is not recognized as a "disease" by the FDA or medical community. The Complaint lacks "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

The Complaint at base is a hodgepodge of legal conclusions dressed up in irrelevant details. For negligence, Plaintiff generically alleges that "[d]efendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution" of Magnevist. Compl. p.19 ¶ 88. But "conclusory allegation of negligence, without any factual support for this cause of action," cannot pass muster. *In re Pamidronate Prod. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012). For strict liability, Plaintiff offers the unadorned conclusion that Bayer provided "inadequate warnings or instruction for use, both prior to marketing and post-marketing," due to "significant risks." Compl. at p.18 ¶ 83. In sum, when it comes to showing causation or injury over her alleged "Gadolinium Deposition Disease," Plaintiff offers nothing "more than labels and conclusions," which fail to state a claim.[2] *See Twombly*, 550 U.S. at 555.

Stripped of rhetoric and labels, Plaintiff's Complaint is reduced to allegations of vague, sprawling symptoms – from "elevated heart rate, loss of appetite, feeling of dehydration," to "sensitivity to other medications and supplements" – with no explanation of how Bayer's product causes any of them. Compl. p.10 ¶ 42. Grouping unrelated afflictions and naming them "Gadolinium Deposition Disease" simply does not suffice to plead that Bayer's product labeling is "the actual and proximate cause of the plaintiff's injury," a requirement for both negligence and strict liability. *Lara v. Delta Int'l Mach. Corp.*, 174 F. Supp. 3d 719, 740 (E.D.N.Y. 2016).

[2] Plaintiff's misleading detour into a decade-old litigation over nephrogenic systemic fibrosis, a condition Plaintiff does not claim to have, also fails to state a viable claim. *See, e.g.*, Compl. p.15 ¶ 69 (describing black box warning for a disease Plaintiff does not allege here).

Nor does Plaintiff offer any facts to say that Bayer should have reasonably foreseen the far-flung symptoms Plaintiff now alleges that Magnevist retention caused her—another requirement for her operative claims. *See Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (N.Y. 1998) (strict liability); *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 480 (N.Y. 1980) (negligence); *see also Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 344 (1928) ("The risk ***reasonably to be perceived*** defines the duty to be obeyed . . . ." (emphasis added)). Tellingly, the Complaint's theory of "GDD" causation is entirely based on patients' "strongly worded letters" to the FDA, *see* Compl. p.16 ¶ 72, coupled with a 2016 article relying on internet forum posts,[3] Compl. p.13 ¶ 59 (citing Semelka et al., *Gadolinium in Humans: A Family of Disorders*, 207 *American Journal of Roentgenology* 229-31 (2016) (article relying on "an online presence" of "patient advocacy groups" as well as a "survey" of "17 patients.")). Furthermore, Plaintiff never alleges when she claims to have used Magnevist, much less that Bayer was on notice of letters to the FDA or non-descript online activity at that point in time.

By contrast, the FDA conducted a thorough review of gadolinium-based contrast dyes, including Magnevist, and concluded both before and after Plaintiff filed her Complaint that, for those "with normal kidney function" as Plaintiff says she has, "[g]adolinium retention ***has not been directly linked to adverse health effects***."[4] *See* 12/19/2017 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm (emphasis added); Compl. p.10 ¶ 42 ("Plaintiff Denise McGrath had normal kidney function…"). Plaintiff's pleading deficiencies are thus all the more striking given the FDA has stated there is no evidence that "Gadolinium Deposition Disease" exists at all. *See* 07/27/15 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm455386.htm (while "trace amounts of gadolinium may stay in the body long-term," the "[a]vailable information ***does not identify any adverse health effects***" (emphasis added)); *see also, e.g., Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.").

Respectfully submitted,

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[3] Courts "may consider [any] documents . . . incorporated in [the complaint] by reference," as Plaintiff has done here. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002); *In re SunEdison, Inc. Sec. Litig.*, 300 F. Supp. 3d 444, 487 n.7 (S.D.N.Y. 2018) (considering news article cited in complaint as having been "incorporated by reference").

[4] The Court should take judicial notice of these official FDA statements since they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," Fed. R. Evid. 201(b)(2), namely, the FDA itself. *See Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 322 & n.9 (S.D.N.Y. 2017) (taking judicial notice of FDA action).